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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,445	04/04/2000	Mark A. Staples	BEH-7354A-Div	5919

34500 7590 09/27/2004

DADE BEHRING INC.
LEGAL DEPARTMENT
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DEERFIELD, IL 60015

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/542,445

Applicant(s)

STAPLES ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 29 January 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): See Attachment.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-3

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☒ Other: See Attachment

ATTACHMENT TO ADVISORY ACTION

Applicants' After-Final Amendment

- 1) Acknowledgment is made of Applicants' after-final amendment filed 11/24/03 is response to the final Office Action mailed 07/08/03. The amendment has been entered.

Status of Claims

- 2) No claims have been amended via the amendment filed 11/24/03.
Claims 1-3 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Terminal Disclaimer

- 5) Acknowledgment is made of Applicants' terminal disclaimer filed 11/24/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US patent 6,171,801.

Objection(s) Maintained

- 6) The objection to the specification made in paragraph 7(b) of the Office Action mailed 09/04/01 is maintained for reasons set forth therein. Applicants have requested previously that amendments to the trademark recitations be done via an Examiner's amendment after the indication allowable subject matter.

Rejection(s) Withdrawn

- 7) The rejection of claims 1-3 made in paragraph 8(a) of the Office Action mailed 09/04/01 under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of the US patent 6,171,801, is withdrawn in light of Applicants' submission of a terminal disclaimer
- 8) The rejection of claims 1-3 made in paragraph 8(b) of the Office Action mailed 09/04/01 under the judicially created doctrine of obviousness-type double patenting over claims 1, 2, 4, 5, 10,

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11, 26 and 27 of the patent, US 6,159,698, is withdrawn in light of Applicants' submission of a terminal disclaimer

Rejection(s) Maintained

9) The rejection of claims 1-3 made in paragraph 10 of the Office Action mailed 12/31/02 and maintained in paragraph 9 of the Office Action under 35 U.S.C § 103(a) as being unpatentable over Tabachnick *et al.* (*Arch. Biochem. Biophys.* 136: 467-479, 1970) in view of Khanna *et al.* (US 4,798,804, already of record), is maintained for reasons set forth therein and herebelow.

Applicants disagree with the Office's position that Tabachnick does not teach away from the present invention. Applicants argue that the ortho derivative in Table II lists a relative affinity of 30, which is substantially less than most of the other derivatives listed. Applicants state that at page 471, column 1, last paragraph, Tabachnick *et al.* teach that a benzoate derivative having a halogen (or nitro) substituent ortho to the carboxyl group exhibits a reduced affinity for HSA compared to a similarly substituted phenol. With this, Applicants submit that Tabachnick teaches away from using the present invention and one skilled in the art would not look to Tabachnick for guidance. Applicants further state that Khanna describes releasing a beta cyclodextrin from digoxin, and that cyclodextrin is not an endogenous protein.

Applicants' arguments have been carefully considered, but are non-persuasive. As set forth previously, if Khanna taught the use of methoxybenzoic acid as a releasing agent for releasing a ligand from a complex with an endogenous protein, Khanna would have been applied under 35 U.S.C § 102 to reject the claims. It is once again emphasized that only claim 2 is limited to the use of the compound where X is O. Tabachnick *et al.* taught the relative affinities of substituted benzoates for HSA, which is an endogenous protein. In the abstract or in Table II, Tabachnick *et al.* did not teach the total absence of affinity of substituted benzoates for HSA. Instead, Tabachnick *et al.* demonstrated that *ortho* substituent shows much better affinity for HSA compared to benzoate and 2, 5 substituted benzoate, and almost the same affinity for HSA as that shown by 2,6-substituted benzoate. Since a reduction in relative affinity is not equivalent to the absence of affinity, Tabachnick *et al.* does not teach away from the claimed invention, but teach the *ortho* substituted benzoate as one of the releasing agents. Moreover, the fact that seventeen years after Tabachnick's disclosure, as opposed to getting discouraged from Tabachnick's teachings, Khanna *et al.* expressly

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taught the successful use of the specific substituted benzoic acid, methoxybenzoic acid, as a releasing agent for releasing a ligand from a complex, is *prima facie* evidence that Tabachnick *et al.* do not teach away from the instant invention. Since the primary reference, Tabachnick *et al.*, already taught the use of an *ortho* substituted benzoic acid derivative in a method for releasing or displacing thyroxine (i.e., a ligand) specifically from a complex with human serum albumin (i.e., endogenous protein) by contacting a medium containing the complex with an effective amount of a substituted, or *ortho* substituted benzoic acid derivative, Khanna does not have to teach or suggest a method to release a ligand from an endogenous protein. The rejection stands.

Remarks

- 10) Claims 1-3 stand rejected.
- 11) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.
- 12) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 13) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding

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should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER